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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: : David Schmidt
Application No. : 10/669,596
Filing Date : September 25, 2003
Title : BIOMOLECULAR WEARABLE APPARATUS

Commissioner for Patents
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INFORMATION DISCLOSURE STATEMENT

The following information is brought to the attention of the U.S. Patent and Trademark Office for purposes of evaluating the present application, including potentially invalidating on-sale activity.

I. LIFEWAVE ENERGY-ENHANCING PRODUCTS WERE APPARENTLY PLACED ON SALE MORE THAN 1 YEAR BEFORE THE APPLICATION WAS FILED

The present application is directed to sealed patches, bracelets, watches, and the like (see Figs. 4-7) to be worn by a user. According to the specification, various organic substances are sealed in a polymer so that nothing enters the body. According to one embodiment a sealed plastic "Band Aid" style patche [0094], or a bracelet, necklace, anklet, or a pendant [0093-94] containing Sioux Honey and Grandma Molasses [0092] "regulates thermodynamic energy-flow within the human body for producing the beneficial effect." [0093] The devices are claimed to affect the "vortex" [0015] of the "human energy field," thus increasing the strength and stamina of the wearer and relieving pain (Abstract), by "passively modulat[ing] the oscillating low energy magnetic field that exists just above the surface of the human epidermal layer." [0063]. The applicant claims that,

“According to the invention . . . an apparatus consisting of orthomolecular organic structures can be designed to passively interact with the human magnetic field for the purpose of creating a system of frequency modulation, much in the same way that radio waves are modulated to communicate audio information.” [0065]. In other words, the applicant claims to have found a way to make organic molecules act as tiny FM radio transmitters that send various beneficial commands to the body. See also Exhibit 2 (“The LifeWave™ Technology patches use the electronic and magnetic features of the body like a cellular radio to transmit information from the patches into the body resulting in specific actions in the cells.”) The applicant claims that the patches represent “cutting-edge, patent pending” “nanotechnology” that constitutes “software for the human body.” (Exhibit 2, 1st page).

Remarkable results are claimed. In Example 1, the devices are claimed to enhance the strength of the wearer by 15%, and the stamina of the wearer by 20%. [0110] – [0114]. In another embodiment, a mixture of Sioux Honey and Grandma Molasses is sealed in a plastic patch, and worn by the user thus providing “relief from a pain for a user.” [sic] [0037]. Other claimed benefits include “relief of sinus congestion” [0097], “relief of menstrual cramps” [0098], and “relief of knee pain from arthritis” [0099]. Similarly, on the applicant’s website, the applicant claims that “Clinical studies show that our LifeWave Energy Enhancer increases fat burning on average by over 20%; the end result of this is and [sic] immediate improvement in energy and stamina.” (Exhibit 2, 2nd page) The applicant claims that the patches are manufactured according to the present application. See Exhibit 2, 3rd page (“We certify that all LifeWave™ patches are manufactured . . . in accordance with the specification in our Patent filing.”).

The present application was filed on September 25, 2003, claiming priority from provisional application No. 60/413,617 filed September 25, 2002. That is, the non-provisional application was filed exactly one year to the date after the

provisional patent application. A copy of the provisional patent application is attached as Exhibit 1 for the Examiner's reference.

A. LifeWave's Pain-Relieving and Stamina-Enhancing and Energy-Enhancing Pendants, Bracelets, and Wristbands Appear To Have Been On-Sale and In Public Use Prior to September 25, 2002

The provisional patent application includes, on the last page of text before the figures, a page of "testimonials" attesting to "amazing" increases in strength and energy, and decreases in pain, from wearing LifeWave medallions, pendants, and wristbands. The testimonials include the following:

Normally a skeptic, and having tried products ranging from copper bracelets to magnet shoe inserts and belts, I am amazed at the results of your pendant. ... [N]ot only does your pendant make my pain go away it also stimulates my energy and stamina levels! Finally, a product that does as advertised and more. Ken G.

My experience with the LifeWave device has been an exceptional one to say the least. Everytime I have worn the medallion I have had significant increases in energy and stamina. Greg C.

(Exhibit 1, 25th page).

According to the provisional patent application therefore, the LifeWave pain relieving pendants were "advertised" prior to preparation and submission of the provisional patent application. It would appear therefore to be certain that the LifeWave pain-relieving and energy- and stamina-enhancing products were "advertised" prior to September 25, 2002. It would also appear that the LifeWave products were in public use prior to the provisional filing date.

It appears therefore that LifeWave pain-relieving and energy- and stamina-enhancing products prepared according to the claimed invention were placed on sale and were in public use before September 25, 2002, which would be more than one year before the non-provisional application's filing date of September 25, 2003.

B. The PTO Must Consider Whether the Provisional Patent Application Contains an Enabling Disclosure of a Device That, When Worn By the User, Dramatically Increases Strength and Energy and Relieves Arthritis Pain and Menstrual Cramps By Regulating A Supposed Human Thermomagnetic Energy Field

The apparent on-sale and public use activity prior to September 25, 2002, which is more than one year before the filing of the present application, would be citable by the Office as prior art under 35 U.S.C. §102(b) against the present application *unless* the provisional patent application complies with 35 USC §112 including the best mode and enablement requirements. The PTO must therefore consider whether the provisional patent application provides the necessary enabling disclosure, and complies with the best mode requirement.

It does not appear that the provisional patent application complies with the best mode and enablement requirements. A reading of the provisional patent application indicates that the purported inventor claims that by placing sugar in one patch or medallion, and amino acids in another patch or medallion, a “vortex flow” is created which improves “energy flow” in a human body because “the human thermal magnetic field twists to the left in the presence of L-amino acid, causing the thermal magnetic field to spin clockwise (inward) which creates a buildup of energy, with this energy assisting in the formation of the new protein structure.” (Exhibit 1, 10th page). This conclusion is questionable and is based on questionable physics. Indeed, the inventor states:

The inventor also declares that he has no knowledge of any prior disclosure which is based on the concept as disclosed. This principle feature in the invention is to be described. Indeed, the normal expectations of such a proposal would be that the structures of the present invention should have no effect or advantage.

(Exhibit 1, 11th page). Because the purported invention is based on highly unconventional physics which even the inventor concedes “should have no effect

or advantage" according to "normal expectations", in view of the relatively thin disclosure and the "amazing" results claimed by way of instantly increased strength and energy and pain relief, the PTO may wish to consider whether the provisional patent application has provided an enabling disclosure such that other skilled practitioners could produce pendants and bracelets which would have the same "amazing" strength-inducing and pain-relieving effects. Indeed, the PTO may wish to carefully consider whether the claimed invention is even operable.

If the PTO concludes that the provisional patent application did not provide a disclosure that complies with the best mode and enablement requirements of 35 USC §112, then the current non-provisional application is not entitled to a filing date of September 25, 2002. If that is the case, and if the testimonials presented in the provisional patent application resulted from products that were placed on-sale or in public use before the filing date of that application which seems to be a near certainty, then the present application would be anticipated under 35 U.S.C. §102(b) by the on-sale and public use activity evidenced by those testimonials.

LifeWave LLC is selling patches today which it claims are "patent pending" (see Exhibit 2, which are pages printed from the LifeWave website located at www.lifewave.com.) LifeWave claims that "all LifeWave™ patches are manufactured ... in accordance with the specifications in our Patent filing." (Id.). LifeWave LLC claims that, just as in the provisional patent application specification:

Nothing enters the body. LifeWave Energy Enhancer is NOT a transdermal patch. This is based on completely new science and is a new approach to energy and well-being.

(Exhibit 2, 5th page). It claims:

LifeWave patches communicate with the body through the human magnetic field. This is known as resonant energy transfer. It sends the message, "transport fat to the mitochondria and make ATP" to the cells. This produces increased energy.

(Id.). It claims:

LifeWave™ [sic] is the world leader in this new and emerging field of organically constructed nano-antennas.

(Exhibit 2, 2nd page). It claims that the patches contain “organic materials such as sugars and amino acids,” and that “when placed above the body the LifeWave patches … [have] been shown to improve energy, relieve pain, enhance sleep and beautify the skin.” (Exhibit 2, 1st page). LifeWave LLC further claims that:

The LifeWave technology patches use the electronic and magnetic features of the body like a cellular radio to transmit information from the patches into the body resulting in specific actions in the cells.

(Exhibit 2, 1st page). In other words, sugar and amino acids act like tiny cellular telephones to send information into the body. LifeWave LLC claims that its tiny cellular telephone technology:

increases fat burning on average by over 20%; the end result of this is and [sic] immediate improvement in energy and stamina.

(Exhibit 2, 2nd page).

The PTO should carefully review the provisional patent application and determine whether that provisional patent application provides a disclosure which would enable someone skilled in whatever art to which honey and molasses patches and/or tiny cellular telephones pertain, to make non-transdermal patches that immediately increase strength and stamina by 15-20% as claimed, relieve arthritis pain as claimed, relieve menstrual cramps as claimed, all by creating a swirling energy vortex thereby regulating a supposed human thermomagnetic energy field.

Additionally, the question of exactly what field this supposedly new science pertains to, and what the level of skill of the ordinary practitioner within this new field is, are valid and pertinent questions. What level of education, for example, does the ordinary practitioner of honey-and-molasses nanotechnology FM transmitter patches that tell the body to burn more fat, possess? What university courses has he taken, and what textbooks are on his shelf? These are

questions that the Office should carefully consider when evaluating the present application in order to determine the level of ordinary skill in the applicable art.

If the provisional patent application does not contain an enabling disclosure to practitioners of honey-and-molasses nanotechnology FM transmitter patches that tell the body to burn more fat, then the current non-provisional patent application should be rejected under the on-sale bar of 35 U.S.C. § 102(b).

II. THE PTO SHOULD CONSIDER WHETHER THE PRESENT PATENT APPLICATION PROVIDES AN ENABLING DISCLOSURE OF SEALED PLASTIC PATCHES THAT, WHEN WORN, PRODUCE DRAMATIC INCREASES IN ENERGY AND STAMINA, RELIEVE PAIN, ENHANCE SLEEP AND BEAUTIFY THE SKIN AS CLAIMED

Completely separate and apart from the question of whether advertising and sale of Lifewave's patches, pendants, and wristbands constitute invalidating on-sale activity under §102(b) that would bar the present patent application, the Office should consider whether the present application provides an enabling disclosure as required by 35 U.S.C. § 112, first paragraph. Lifewave LLC claims that the patches that it is selling:

contain the LifeWave™ technology. A blend of water, oxygen, amino acids, sugars and organics are applied to a polyester fabric and sealed within a polymer shell. The active materials are processed and applied to a substrate so as to form a nano-scale organic molecular antenna.

(Exhibit 2, 2nd page). LifeWave LLC claims extraordinary results for its patches, which it claims are made according to the patent application. Lifewave LLC claims, "LifeWave has been shown to improve energy, relieve pain, and enhance sleep and beautify the skin." (Exhibit 2, 1st page) LifeWave LLC further claims that:

Clinic studies show that our LifeWave Energy Enhancer increases fat burning an average by over 20%; the end result of this is and [sic] immediate improvement in energy and stamina. More life-enhancing products are on the way.

(Exhibit 2, 2nd page). LifeWave LLC further claims that its patches contain:

Nanotechnology [that] creates beautiful skin from the inside out through detoxification, better hydration and skin renewal.

(Exhibit 2, 8th page). LifeWave further claims for its “Rest Quiet” patch:

Our patent pending technology has been shown to produce dramatic heating and cooling effects on the human body. When this patch is placed over specific acupuncture points the body relaxes. . .

Nothing enters the body. Rest Quiet is a new organic nanotechnology patch that helps you to relax without drugs. Research indicates that Rest Quiet helps the body’s own natural meridians balance when the patch is applied to specific acupuncture points. This helps achieve a quite, restful sleep and a great, energized day to follow.

(Exhibit 2, 3rd page). LifeWave LLC even claims that:

[O]ne patch on your right temple actually stops you from snoring . . . [and] enables couples to sleep together.

(Exhibit 2, 6th page) (supposed testimonial from “Sheila Bryan”).

In view of the extraordinary claims made by LifeWave LLC and by its founder and the inventor of the present application David Schmidt who previously claimed in the provisional application filing to be a doctor of something,¹ that its sealed products contain organic substances that, when placed near the body, produce dramatic and immediate increases in strength and stamina, and reduce pain, and stop snoring, and beautify the skin, the PTO should carefully consider whether the present application provides an enabling disclosure such that practitioners in the field could replicate the extraordinary results claimed. This

¹ In the letter accompanying the provisional patent application filing, applicant David Schmidt represented himself to be “Dr. David Schmidt” (Exhibit 1, 3rd page) and affixed his signature above that title. (Id.) However, the website of LifeWave LLC does not currently list Mr. Schmidt as “Dr. David Schmidt.” The website does, however, state that “David Schmidt – CEO (The Visionary)” was bestowed an “honorary doctor” from “the International Hall of Fame” (Exhibit 2, 9th page), whatever that organization might be.

concerned member of the public respectfully submits that because LifeWave LLC claims extraordinary results for the patches, the PTO should require extraordinary proof of efficacy as claimed, and extraordinary proof of enablement to ordinary practitioners in the field, before granting the present application.

Indeed, the PTO may wish to consider whether the named inventor “Dr.” David Schmidt is using the patent application process to further a goal that was not intended by Congress.

CONCLUSIONS

Because LifeWave is currently selling its sealed plastic sugar patches based on claims that the patches are based on “cutting-edge, patent pending technology” which even the inventor concedes “should have no effect or advantage” according to “normal expectations,” the concerned member of the public submitting this Information Disclosure Statement submits that the PTO should carefully consider whether the current application and the provisional patent application from which it claims an effective filing date, comply with the best Mode and Enablement Requirements for producing such “amazing” patches, and whether the testimonials for the “amazing” pendants and medallions evidence invalidating on-sale and public use prior art under 35 USC §102(b).

Respectfully submitted,

A Concerned Member of the Public